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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,209	BERGHOF ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is written in response to applicant's correspondence submitted 7/2/02 and 8/22/03. Claims 3-14 and 24-51 are cancelled and claims 52-69 have been added. Claims 52-69 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

2. Applicant is reminded that SEQ ID NO: 5 as recited in claim 69 is withdrawn from prosecution as being non-elected. Claim 69 was examined only insofar as it recites SEQ ID NO: 3 and SEQ ID NO: 4.

3. The drawings are approved with regard to formal matters. However, as noted below, the are objected to as containing new matter.

Sequence Rules

4. The CRF filed 7/13/01 has been entered into the STIC database. The global misspelling of "unknown" was corrected throughout the CRF.

5. The sequence listing is redundant. The sequences listed as SEQ ID NO: 1, SEQ ID NO: 13 and SEQ ID NO: 19 are identical to one another. Furthermore, the sequences listed as SEQ ID NO: 14 and SEQ ID NO: 15 are also identical to one another. Such an inclusion is confusing. Correction is required. The amendment filed 7/2/02 directed cancellation of SEQ ID NO: 13, 14, 15, and 19 to the sequence listing, however this is not a proper amendment to the sequence listing in accordance with the sequence rules. In accordance with the sequence rules, a new sequence listing and CRF must be submitted if applicant wishes to modify the sequence listing.

Specification

6. The amendment filed under article 34, 15 October 1999 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. Furthermore, amendments filed under Article 34 "must not go beyond the disclosure of the international application as filed (MPEP 1871)." The added material which is not supported by the original disclosure is as follows: Figures 1-10 constitute new matter because they each recite sequence that are not supported by the specification as originally filed. In this application filed under 35 USC 371, the specification as originally filed is considered to be the specification filed as the international application. The original specification does not discuss any sequences other than those disclosed herein as SEQ ID NO: 1-5. Therefore, the amendment filed 7/13/01 which includes SEQ ID NO: 6-12 and 14-18 also introduces new matter to the disclosure. The sequences identified as SEQ ID NO: 13 and 19 are not new matter because they are identical to SEQ ID NO: 1.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Second Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 53-66 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 is unclear. It is not clear if applicant is claiming kit comprising a probe comprising a nucleic acid that differs from SEQ ID NO: 1 by at least one nucleotide, or if applicant is claiming a kit comprising a probe that could identify and discriminate between SEQ ID NO: 1 and a sequence that differs from SEQ ID NO: 1. The structural limitations of the claim are not clearly set forth. The claim is generally narrative in form and it is difficult to determine what is required in the claimed kit. For example, it is not clear what the phrase "by a differing nucleic acid sequence in at least on position in SEQ ID NO: 1" is meant to modify. Claim 54 recites similar language and is also unclear for the same reasons, and thus so are claims 55-57 which depend from claim 54.

The phrase "said nucleic acid molecule primer and/or probe" in claim 55 lacks proper antecedent basis in the claim because claim 54, from which claim 55 depends, refers to more than one such primer or probe and it is not clear which one is being referred to in claim 55. Claims 59-66 are indefinite over similar recitations in claims 59, 60, 61, and 64 as these all depend from claim 52 which also recites more than one primer or probe.

Claim 56 depends from claim 55, but it is not clear how it further limits claim 55, or if it does further limit claim 55. Claim 55 requires that the claimed nucleic acid comprise SEQ ID NO: 1, but claim 56 merely recites portions of SEQ ID NO: 1 that would be inherently included within a nucleic acid that comprises SEQ ID NO: 1. It is not clear if claim 56 is drawn using open claim language (as in claim 55) or closed claim language as no transitional language is

being used. If the claim is meant to be claiming nucleic acids consisting of the fragments recited, then the claim is an improperly dependent claim because the claim would not be including all of the limitations of the parent claim which requires all of SEQ ID NO: 1. Likewise, claim 57 is rejected because it is confusing in the same way.

Claim 58 is indefinite because it is not clear how or if it further limits the claim from which it depends. First, the claim repeatedly refers to "the nucleic acid molecule primer and/or probe" which lacks proper antecedent basis because claim 52 requires "more than one nucleic acid molecule primer and/or probe" so it is not clear which is THE molecule being referred to in claim 58. Furthermore, it is not clear how applicant is intending to further limit the claims in the further recitations of claim 58, as it cannot be determined which nucleic acid is being referred to. It is not clear if the claim is narrowing or broadening the scope of claim 52, as many of the recitations appear to require less than claim 52 itself requires (only 8 successive nucleotides of the probe of claim 52, for example).

Claims 64-66 are indefinite over the recitation "analogous nucleotides" because it is not clear what is meant by an analogous nucleotide. This phrase is not a term of art, and the specification does not appear to define the phrase, though it uses the phrase on page 10.

First Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 52-54, 58, 59, and 60-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a nucleic acids as well as kits for the analytical detection of Staphylococcus aureus which comprise nucleic acid probes and/or primers.

Claim 52 minimally requires that at least one probe in the kit comprises 10 successive nucleotides of the region comprising position 54 to 83 of SEQ ID NO: 1 or nucleotide positions 100-166 of SEQ ID NO: 1, and that the sequence be able to selectively hybridize to RNA or DNA of S. aureus. Claim 53 does not set forth any structural requirement for the probes in the claimed kit, merely requires that they be able to hybridize to or amplify S. aureus and distinguish between S. aureus and a bacteria that differs by at least one base pair in SEQ ID NO: 1. The claim does not further define the "bacteria not to be detected." Claim 54 is similar to claim 53 but delineates specific regions of SEQ ID NO: 1 where the one base pair difference must occur. Claim 58 depends from claim 52 and recites probes that have only 8 or 9 successive nucleotides of the probe of claim 52 or are 90% homologous to the probe of claim 52. The genus encompassed within the instant claims is quite large, encompassing nucleic acids that have fragments of SEQ ID NO: 1 embedded in any framework, as well for claim 53-54 any possible nucleic acid that would meet the functional limitations of the claims, as the claim does not even require that the claimed nucleic acid encompass SEQ ID NO: 1 or portions thereof.

The specification provides SEQ ID NO: 1, and identifies specific regions of SEQ ID NO: 1 have high variability compared to other Staphylococcal species, and are therefore useful for determining species specific probes (p. 15). SEQ ID NO: 1 is from the species S. aureus. The specification does not provide the sequence corresponding to SEQ ID NO: 1 for any other

species. Furthermore, in the examples, the specification clearly demonstrates that the nucleic acids of the instant invention are only able to detect S. aureus.

The specification provides no guidance as to what differences between in SEQ ID NO: 1 and some other sequence would be useful for distinguishing between bacteria to be detected and not to be detected. This genus of bacteria not to be detected in enormous given all ofhte different types of bacteria known. Thus, applicant has express possession of a limited number of species (a probe consisting of SEQ ID NO: 1, as well as probes which consist of fragments of SEQ ID NO: 1) in a genus which comprises hundreds of millions of different possibilities. It is noted that from within this single exemplified sequence three additional probes are given, named as SEQ ID NO: 2-4. These are also considered to be properly described.

With regard to the written description, many of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No:s which, include modifications by permitted by the % identity language as well as for "base pair differences" for which no written description is provided in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acids of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID No: 1 but possessing one such that a different nucleic acid sequence is retains S. aureus detecting function or such that the nucleic acid has the ability to detect other species of Staphylococcus.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 52-63 and 67-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Kunsch *et al.* (CA 2194411).

This document is a "laid open" Canadian patent application. When the application is "laid open" all parts of the application as filed become available to the public. In the instant case, the Canadian patent office did not publish the sequence listing for CA 2194411 A1. However, the full sequence listing was available to the public on the day the application was laid open. It is assumed that this sequence listing is identical to that in the CA 2194411 A1 application.

Kunsch *et al.* teach kits comprising more than one nucleic acid probes, wherein at least one of the nucleic acid molecules hybridizes selectively to the RNA or DNA of S. aureus.

Kunsch *et al.* provide, in 5,191 sequences, polynucleotides of the genome of S. aureus (p. 7). Kunsch *et al.* teach fragments that can be used to diagnose S. aureus (DF's) (p. 8, line 8) and kits which comprise these fragments (p. 42, line 24-p. 44, line 12). Many of the sequences taught by Kunsch *et al.* meet the limitations of the instant claims.

For example, SEQ ID NO: 3803 taught by Kunsch *et al.* comprises SEQ ID NO: 1. Instant SEQ ID NO: 1 is the complement of 26-196 of Kunsch *et al.*'s SEQ ID NO: 3803.

As another example, SEQ ID NO: 4725 taught by Kunsch *et al.* comprises part of nucleotides 54-83 of instant SEQ ID NO: 1, but is shorter than SEQ ID NO: 1. Nucleotides 106-134 of SEQ ID NO: 4725 are identical to nucleotides 54-82 of SEQ ID NO: 1. Therefore, SEQ ID NO: 4725 also comprises SEQ ID NO: 2.

As a third example, SEQ ID NO: 5094 taught by Kunsch *et al.* comprises nucleotides 100-166 of instant SEQ ID NO: 1, but is shorter than instant SEQ ID NO: 1. Kunsch *et al.*'s SEQ ID NO: 5094 consists of 51 nucleic acids which are identical to nucleotides 83-135 of instant SEQ ID NO: 1. Therefore, SEQ ID NO: 5094 also comprises SEQ ID NO: 4 which are found at positions 102-121 of SEQ ID NO: 1.

These sequences would hybridize selectively to S. aureus, and each contain at least ten nucleotides from position 54 to 83 of SEQ ID NO: 1, or position 100 to 166 of SEQ ID NO: 1, or sequence complementary to these regions. These sequences could be used to distinguish between S. aureus and other sequences via a hybridization assay. At least one of these sequences "has" (i.e. comprises) instant SEQ ID NO: 1.

Kunsch *et al.* provide many additional nucleic acids whose sequences meet the limitations of at least one, if not all, of the rejected claims. Specific identification of these nucleic acids would have been duplicative of the three mentioned examples.

With regard to claim 52, at least one of the nucleic acid molecules taught by Kunsch *et al.* is comprised of at least 10 successive nucleotides of the region comprising nucleotide position 54 to 83 of SEQ ID NO: 1 and nucleotide position 100 to 166 of SEQ ID NO: 1, as SEQ ID NO: 3803 taught by Kunsch *et al.* comprises all of SEQ ID NO: 1 and thus comprises both of these portions.

With regard to claims 53, 54, 55, 56 and 57, at least one of the probes taught by Kunsch *et al.* is considered to be adapted to selectively hybridize and/or amplify RNA or DNA from *S. aureus* as they are all fragments of the *S. aureus* genome, and further is "adapted to" distinguish between bacteria to be detected and bacteria not to be detected by a differing nucleic acid sequence it at least one base position in SEQ ID NO: 1 in the genomic DNA and/or RNA of said bacteria to be detected and said bacteria not to be detected. A nucleic acid comprising SEQ ID NO: 1 would be adapted to distinguish between SEQ ID NO: 1 and a sequence that differs from SEQ ID NO: 1 by at least one nucleotide. Kunsch *et al.* teach such a molecule. This applies to claim 56 because the recited positions within the claim are contained within SEQ ID NO: 1. This applies to claim 57 because each of SEQ ID NO: 2, 3, and 4 are portions of SEQ ID NO: 1. Claims 56 and 57 depend from claim 55, and thus must include all of the limitations of claim 55 which requires that the probe comprises SEQ ID NO: 1 in its entirety.

With regard to claim 58, at least 10 successive nucleotides of the sequence of the nucleic acid probe are identical to the nucleic acid probe of claim 52, as at least one of the nucleic acid

molecules taught by Kunsch *et al.* is comprised of at least 10 successive nucleotides of the region comprising nucleotide position 54 to 83 of SEQ ID NO: 1 and nucleotide position 100 to 166 of SEQ ID NO: 1, as SEQ ID NO: 3803 taught by Kunsch *et al.* comprises all of SEQ ID NO: 1 and thus comprises both of these portions.

With regard to claim 59, Kunsch *et al.* teach that the nucleic acids of their invention include both single and double stranded molecules (p. 19, lines 21-22).

With regard to claim 60, the molecules taught by Kunsch *et al.* are DNA or RNA (p. 19, lines 21-22).

With regard to claims 61-63, all nucleic acid molecules, including those taught by Kunsch *et al.* comprise groups for an indirect or direct reaction, provided the proper reacting partners are present. For example, nucleic acids can be extended or cleaved, which would be encompassed within such reactions, and would also be enzymatic reactions (claim 62) that utilize an enzyme (claim 63).

With regard to claim 67, the molecules taught by Kunsch *et al.* include a nucleotide probe comprising SEQ ID NO: 1. The nucleic acid taught by Kunsch *et al.* as SEQ ID NO: 3803 is a nucleic acid comprising SEQ ID NO: 1. With regard to claim 68, this nucleic acid molecule comprises positions 54 to 83 of SEQ ID NO: 1 and nucleotide positions 100-166 of SEQ ID NO: 1 as it comprises SEQ ID NO: 1 in its entirety, and thus also comprises all portions of SEQ ID NO: 1. With regard to claim 69, Kunsch *et al.* teach a nucleotide probe having SEQ ID NO: 3 and SEQ ID NO: 4, as these are all also fragments of SEQ ID NO: 1, which Kunsch *et al.* teach in its entirety.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunsch *et al.* in view of Buchardt *et al.* (Trends in Biotechnology, 1993, 11(9), 384-386).

Kunsch *et al.* teach kits comprising more than one nucleic acid probes, wherein at least one of the nucleic acid molecules hybridizes selectively to the RNA or DNA of S. aureus. Kunsch *et al.* provide, in 5,191 sequences, polynucleotides of the genome of S. aureus (p. 7). Kunsch *et al.* teach fragments that can be used to diagnose S. aureus (DF's) (p. 8, line 8) and kits which comprise these fragments (p. 42, line 24-p. 44, line 12). Many of the sequences taught by Kunsch *et al.* meet the limitations of the instant claims.

For example, SEQ ID NO: 3803 taught by Kunsch *et al.* comprises SEQ ID NO: 1. Instant SEQ ID NO: 1 is the complement of 26-196 of Kunsch *et al.*'s SEQ ID NO: 3803. Thus, at least one of the nucleic acid molecules taught by Kunsch *et al.* is comprised of at least 10

successive nucleotides of the region comprising nucleotide position 54 to 83 of SEQ ID NO: 1 and nucleotide position 100 to 166 of SEQ ID NO: 1, as SEQ ID NO: 3803 taught by Kunsch *et al.* comprises all of SEQ ID NO: 1 and thus comprises both of these portions.

Kunsch *et al.* do not discuss analogous nucleotides.

Buchardt *et al.* teach that peptide nucleic acid probes are resistant to nuclease cleavage and protease attack and are promising as biomolecular and diagnostic probes (ABSTRACT, for example). Peptide nucleic acids are made up of "analogous nucleotides" that are not naturally occurring in bacteria.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the detection fragment taught by Kunsch *et al.* so as to have used PNA instead of DNA as a detection fragment, thereby to have replace all of the sequence of the probe with peptide nucleic acid, in order to obtain the benefits of using a PNA probe as taught by Buchardt. Such a modification would have encompassed modifying 10% of the probe and 1 or two nucleotides of the probe. Indeed modifying the entire detection fragment encompasses both 10% and 1 or 2 nucleotides as recited in claims 64 and 65.

Response to Remarks

With regard to the objection to the specification, applicant argued in the response that these drawings were part of the specification originally filed in the PCT application, however, the drawing which support the objected to new matter were filed as amendments to the originally filed specification, and themselves represent new matter. Thus, the drawings and the sequences depicted in them remain objected to as being new matter.

The 112 2nd rejections are withdrawn as the claims to which they referred have been cancelled. New 112 2nd rejections are set forth to address the newly filed claims.

The rejection under Written Description is applied to the newly filed claims.

With regard to the rejections under 102(b), Applicant points out that the instant invention is directed towards a kit for the selective analytical detection of S. aureus, and suggests that prior to the instant invention the art did not provide for defined non-conserved regions for the discrimination of S. aureus. However, this is not persuasive. As a first point, the claims do not claim all non-conserved regions for the discrimination of S. aureus, and so the breadth of this statement is not fully addressed. Instead, the claims are drawn to kits and nucleic acids that comprise or hybridize to SEQ ID NO: 1 or portions of SEQ ID NO: 1. These are addressed in the art rejections.

Applicant argues that Kunsch *et al.* does not anticipate the instant invention because Kunsch *et al.* does not "teach or suggest, *inter alia*, the discrimination of Staphylococcus aureus from other Staphylococcus species (response, p. 10, third paragraph)." However, applicant is reminded that the instant claims are drawn to product claims, not method claims, and the recitation in the claims describing the intended use of the products is just that, an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In the instant case, the nucleic acids taught by Kunsch *et al.* are no different from the instantly claimed nucleic acid molecules (see

MPEP 2111.02), and they would function for the intended use set forth by applicant, whether or not Kunsch *et al.* teach this use.

Applicant argues that the rejection under 102(b) should not apply to the newly filed claims because Kunsch *et al.* does not teach or suggest instant SEQ ID NO: 1. It is noted that applicant appears to be arguing that Kunsch *et al.* does not teach a nucleic acid **CONSISTING OF** SEQ ID NO: 1. This is a limitation that is not present in any one of the claims recited herein, and a limitation that would greatly change the scope of the instant claims and require further search and consideration. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Such a claim may not be anticipated by Kunsch *et al.*, but if it were presented new rejection may be set forth under 103. As it is, the claims encompass many, many nucleic acid embodiments, as they require only that the claimed probe be "comprised of" of ten nucleotides of portions of SEQ ID NO: 1 (claim 52). The language "comprised of" as recited in claim 52, for example, is read as open claim language equivalent to comprising, which requires the claimed structure be present but can be flanked by additional sequences. Furthermore, claim 53 does not require any structural limitation, merely that the probe have the ability to distinguish between two bacteria that wherein the one not to be detected differs from SEQ ID NO: 1. The nucleic acids taught by Kunsch *et al.* certainly would meet that limitation. Independent claim 54 requires that the claimed kit contain a nucleic acid probe that has the ability to distinguish between two bacteria that wherein the one not to be detected differs from portions of SEQ ID NO: 1. A nucleic acid which comprises all of SEQ ID NO: 1

(including the recited portions) meets this claim. This interpretation of the claim is supported by the overt use of the language "comprising" in claim 55 which depends from claim 54.

Applicant argues that SEQ ID NO: 3803 taught by Kunsch *et al.* comprises more than just SEQ ID NO: 1, and this is not disputed. The language of the instant claims encompasses such a nucleic acid. Applicant further argues that there is no teaching or suggestion that SEQ ID NO: 3803 can be used for the differentiation of S. aureus from other Staphyloccous species or species of other genera. First, as discussed, this is a intended use of the claimed polynucleotide. Further, there is no reason to believe that the nucleic acids taught by Kunsch *et al.* would not be useful for the detection of S. aureus as they are themselves fragments of the S. aureus genome, and Kunsch *et al.* specifically teach in their disclosure they can be used for detection of S. aureus. Finally this intended use is not even recited in the claims.

Applicant further points our that SEQ ID NO: 4785 differs from instant SEQ ID NO: 1 in at least nucleotides 1 to 105, and therefore does not belong to the 23S/5S intergenic region. However, this is irrelevant to the instant claims which never recite this region. Claim 52, for example, requires only that the claimed kit comprise a probe that comprises at least 10 successive nucleotides of instant SEQ ID NO: 1. As discussed in the rejection, both SEQ ID NO: 4785 and 5094 taught by Kunsch *et al.* meet this limitation.

The examiner is not relying on the doctrine of inherency to meet the instant claims, but instead has relied on the structural limitations provided in the claims and compared those to the nucleic acid sequences provided in the disclosure of Kunsch *et al.* Applicant has provided no argument or evidence which would suggest that the nucleic acids of Kunsch *et al.* are not "adapted to" or capable of achieving the intended uses set forth in the product claims herein. In

order to anticipate the claimed products, Kunsch *et al.* are not required to disclose the same intended use, though they do say that their nucleic acids are useful for detection S. aureus, as discussed in the rejection.

For at least these reasons, the rejection under 102(b) is applied to the newly filed claims as discussed herein.

New 103 rejections are set forth to address some of the new claims.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Green *et al.* (GenBank L36472, 11 November 1994) provide a nucleic acid sequence which comprises the 5s-23s spacer region of Staphylococcus aureus. The sequence taught by Green *et al.* comprises instant SEQ ID NO: 1.

17. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Switzer whose telephone number is 703 306 5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703 308 1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305 3592 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

Juliet C. Switzer
Art Unit 1634

October 29, 2003